Candidate for Proposition 65 Listing via the Authoritative Bodies Mechanism Found Not to Meet the Scientific Criteria (22 CCR 12306(g)): Dimethylamine Dicamba (CAS No. 1918-00-9)

Office of Environmental Health Hazard Assessment February, 2000

The U.S. Environmental Protection Agency (U.S. EPA), an authoritative body for purposes of Proposition 65 (22 CCR Section 12306(l)), identifies chemicals as causing developmental or reproductive toxicity in implementing its Toxic Release Inventory (TRI) program (*i.e.*, Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA)). On this basis the U.S. EPA, in 1994, added a number of chemicals to the TRI list and published its findings in the *Federal Register* (**59:**1788-1859, 1994 and **59:**61432-61485, 1994). The Office of Environmental Health Hazard Assessment (OEHHA) has reviewed the bases for these TRI chemical additions in the context of the regulatory criteria governing Proposition 65 listing via the authoritative bodies mechanism (Title 22, California Code of Regulations, Section 12306 (22 CCR 12306)).

OEHHA determined for several TRI chemicals that the 22 CCR 12306 regulatory criteria were met and is in the process of placing these chemicals on the Proposition 65 list of chemicals known to cause reproductive toxicity. As described below, OEHHA has determined that scientific criteria for "as causing reproductive toxicity" given in regulation (22 CCR 12306(g)) were not satisfied for dimethylamine dicamba (CAS No. 1918-00-9), which was added by U.S. EPA in 1994 to the TRI list on the basis of developmental toxicity.

Two rabbit teratology studies serve as the basis for the TRI identification of developmental toxicity, and the consistency with data from studies on dicamba was also noted (*Federal Register* **59:**1788-1859, 1994). Dicamba, previously a candidate for listing under Proposition 65 on the basis of a TRI identification of developmental toxicity, has been found not to meet the scientific criteria for listing on this basis (*California Regulatory Notice Register*, March 19, 1999, Register 99, No. 12-Z).

OEHHA has retrieved and examined the studies cited for dimethylamine dicamba, and has found that they were conducted as a pilot and a main study, submitted to U.S. EPA by Velsicol Chemical Company (1978, MRID No. 00028236). OEHHA has determined that the main study, conducted using technical dicamba (Banvel-D), was the same study cited to support the TRI identification of dicamba. As noted earlier by OEHHA (1999), significant deficiencies are identified for this study, including: 1) the combination of data from two components of the main experiment because there were not enough pregnancies in the first component; 2) no individual data being provided; 3) numerous deaths across all treatment

Candidate for AB Listing Not Meeting 22 CCR 12306 Criteria

and control groups associated with "pulmonary involvement"; and 4) no analysis of the purity of the dosing solution. The effects cited in TRI for the pilot study, early and late fetal resorptions, were not dose-related. The pilot study therefore does not add evidence to support the listing of dimethylamine dicamba. Thus, as with dicamba, OEHHA has determined that the scientific criteria (22 CCR 12306) for listing dimethylamine dicamba via the authoritative bodies listing mechanism have not been met.

Reference

Office of Environmental Health Hazard Assessment (OEHHA, 1999), Mechanism Found Not to Meet the Scientific Criteria (22 CCR 12306(g)), OEHHA, California Environmental Protection Agency, Sacramento, California, March.